

K013627 SONOACE SA-8000 DIAGNOSTIC ULTRASOUND SYSTEMNov 16, 2001
11 days to decisionK013627 · Product code: IYN · Radiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 5, 2001
Decision date	Nov 16, 2001
Days to decision	11 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Medison America, Inc.
Location	Fremont, CA, US
Contact	A. ROBERT DEPALMA
510(k) history	21 submissions · 21 cleared · 1993-2003

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